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REMARKS

Claims 1-39 were pending in the present application. Claims 28-34 have been previously withdrawn from consideration and claim 15 was previously cancelled. By virtue of this response, claims 16 and 17 have been cancelled, claims 1, 18, and 35 have been amended and new dependent claim 40 has been added. Accordingly, claims 1-14, 18-27 and 35-40 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

Telephone Interview of January 10, 2007

The Applicant's thank the Examiner for the telephone interview on January 10, 2007, during which the US 4,590,934 reference by Malis et al. was discussed. As requested by the Examiner, the Applicants have herein set forth their arguments with respect to Malis, and have further amended their claims to clarify distinctions between prior art systems and the systems claimed. Further, Applicants have amended the claims to clarify the distinction over Malis, as suggested.

Claim Rejections Under 35 U.S.C. §103

Claims 1-27 and 35-39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,533,781 to Heim et al. ("Heim") in view of US 4,590,934 to Malis et al. ("Malis").

Applicants respectfully disagree. Neither Malis nor Heim teach or suggest all of the features recited in the claims as amended. In particular, independent claims 1 and 35 recite a source of pulsed electrical energy that is configured to apply a plurality of bursts of pulses separated by a burst interval of greater than about 1 ms (during which no pulses are present) to an electrically conductive blade, wherein the duration of the burst of pulses is 1 ms or less. Neither Malis or Heim, or their combination, teach or suggest a source of pulsed electrical energy that is configured to apply a plurality of bursts or pulses that are separated by a burst interval of greater than 1 ms, wherein the duration of the burst of pulses is 1 ms or less.

The output of the source of pulsed electrical energy of Malis is described in Fig. 18 of Malis. As shown in Fig. 18(a) of Malis, the interval between these burst of ramped pulses is between 11 and 51 μsec. Thus, the longest duration between bursts taught by Malis is 51 μsec, which is not a burst interval greater than 1 msec, as recited by the Applicants' pending claims. Another waveform is shown in Fig. 18(f) of Malis. The 'burst' of pulses shown in Fig. 18(f) has a duration of 6 ms, and is therefore not "1 ms or less," as recited by Applicant's claims 1 and 35 (Applicants further point out that Malis expressly describes Fig. 18(f) as an example of an "objectionable" output that is to be avoided, and describes how the Malis device is expressly configured to avoid this output. See Malis col. 10: 35-60). Furthermore, the Heim reference does not teach a source of pulsed electrical energy.

Thus, neither Malis nor Heim suggest a source of pulsed electrical energy that is configured to apply a plurality of bursts of pulses separated by a burst interval of greater than about 1 ms, wherein the duration of the burst of pulses is 1 ms or less, as recited by the Applicants' claims. Furthermore, it would not be obvious to further modify Malis and/or Heim to achieve a source of pulsed electrical energy having these properties. Modification of Malis to provide a source of pulsed electrical energy having the parameters recited in the Applicant's claims would require undue experimentation and further, the pulsing regime recited in the claims was identified by the Applicants because it has unexpected and advantageous results, namely tissue cutting with micrometer-scale collateral damage, greatly exceeding all other electrosurgical instruments.

The recited range of pulse durations which the energy source is configured to apply is fully supported by the specification. Furthermore, the Applicant has previously described the unexpected benefit of this range in the Applicants' co-pending patent application (US Serial No. 10/825,716). In particular, Fig. 4B of that application and the accompanying text describe a range of pulse durations (42' shown in Fig. 4B) in which the size and rate of formation of the vapor cavity, as well as the heat diffusion into the tissue are minimized. On the short end of the time scale (e.g., the left side of Fig. 4B) optimal range is limited by the mechanical damage by vapor bubbles that have significant impact at pulse durations of shorter than 50 μs (e.g., 38' in Figure 4B). On the other hand, at long pulse durations (line 40' on the right side of Fig. 4B) tissue damage is dominated by

heat diffusion. As described, the Applicants have found that pulse durations in this rather narrow window, between several tens of microseconds to a millisecond, provide a minimal collateral damage by minimizing both the mechanical and thermal damage. Outside of this window, there is substantial tissue damage. Furthermore, the Applicant has also found that the burst interval of the waveform recited in the claims prevents accumulation of heat in the tissue from the train of repetitive bursts. The Applicants believe that this is achieved by separating the bursts with intervals exceeding the burst duration and the heat diffusion time from the electrode.

Both parameters, duration of the burst and delay between them are important; as described in the instant specification, having burst separation exceeding 1 ms allows electrosurgical cutting with the electrically conductive blade at very low duty-cycle, and consequently, low average power. Cutting action begins and ends in each burst, and the duration between the bursts of 1 ms or longer allows for cooling of the tissue. In this way, accumulation of thermal energy from burst to burst is prevented, which results in very narrow zone of thermal damage at the edges of the cut.

As discussed above, Malis does not describe a device configured to apply a plurality of bursts of pulses separated by a burst interval of greater than 1 ms, where the duration of the burst of pulses is less than 1 ms. As described above, all of the waveforms described in Malis (e.g., Fig. 18(a), Fig. 18(f)) will lead to greater thermal damage due to either heat diffusion into tissue during the long burst, or due to accumulation of heat in a fast sequence of bursts due to insufficient time for heat relaxation.

One of skill in the art could not, without an unreasonable amount of experimentation, modify the teaching of Malis (particularly in combination with Heim) to create a source of pulsed electrical energy configured to apply a plurality of bursts of pulses separated by a burst interval of greater than about 1 ms during which no pulses are present and wherein the duration of the burst of pulses is 1 ms or less. The range of pulse parameters taught by Malis are quite different (and non-overlapping) with the range for both pulse duration and inter-pulse interval recited by the Applicant's source of pulsed energy.

As described in the Applicant's disclosure, a source of pulsed electrical energy having the pulsing regime as recited by the Applicants' claims was developed to produce electrosurgical plasma cutting that result in less damage due to minimization of two independent effects: heating of the material and mechanical damage by vapor bubbles. Typical electrosurgical cutting applies continuous RF energy, as described in Malis (see Malis, col. 9:40-42, "Thus, in the Cut mode the output of driver 58 is a continuous 1 MHz pulse stream without any damping, frequency sweep, or dead zones."). In contrast, the Applicant's device applies a series of brief (less than 1 ms) bursts of pulses with a long (greater than or equal to 1 ms) interval between bursts.

The source of pulsed electrical energy in the Applicant's pending claims is configured to provide a pulsing regime that is specific to these two ranges: both the inter-burst interval (of 1 ms or greater), and the pulse-burst duration (of less than about 1 ms). It is this combination of ranges that are effective for cutting tissue as described by the Applicant. Settling on this combination of ranges for these two parameters requires more than mere 'routine optimization of ranges,' at least because the relationship between these two parameters and the ability to cut material using an electrode provided with the pulsed output is complex and non-linear. In point of fact, the ranges recited in the Applicant's claims were selected by the Applicant's after a great deal of research and analysis. As mentioned above, a discussion of this analysis was published in co-pending U.S. patent application US Serial No. 10/825,716 (published as US 2004/0199157).

Thus, the configuration for the source of pulsed electrical energy (e.g., the pulse duration) is based on the unexpected and beneficial result that the cavitation bubble size, energy deposition and heat diffusion are a complex function of the pulse duration. As the applicants' described, there is an optimal range of pulse duration within which both, the mechanical damage by the bubbles and thermal damage by heat diffusion can be smaller than the initial energy penetration zone determined by the electrode size. As the radius of the bubbles decreases at durations exceeding ten microseconds, the length to which heat diffuses around the cutting electrode is first negligible, and then increases dramatically, exceeding the initial energy deposition zone at pulse durations exceeding 1 ms. The Applicants have applied this discovery of this relationship to configure the source of pulsed electrical energy to provide a pulse duration range during which damage to a tissue

due to the cavitation bubbles (e.g., the left side of Fig. 4B) and damage to a tissue from heat diffusion (the right side of Fig. 4B) are minimized.

The Applicants respectfully reiterate that Malis does not suggest the recited ranges, and further. Since neither Heim nor Malis teach or suggest all of the features recited in claims 1-27 and 35-39, these claims cannot be obvious in view of these references. Furthermore, it would not be obvious to modify Malis to provide a source of pulsed electrical energy as recited by the Applicant's claims, because the parameters for burst duration and burst interval recited in the claims result from the Applicant's own unexpected results, and attempts at modification would require undue experimentation. The Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection of claims 1-27 and 35-39 for at least the reasons give above.

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CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 595992000600. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 16, 2007

Respectfully submitted,

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